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WASHINGTON, DC 20005

EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,669

Applicant(s)

WACHENDORFF-NEUMANN ET AL.

Examiner

Sabiha Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Art Unit: 1616

Final Office Action

Claims 6-9 are pending. No claim is allowed at this time.

Summary of this Office Action dated Saturday, October 27, 2007

1. 35 USC § 103(a) Rejection
2. Declaration and the data in Specification
3. Conclusion
4. Communication

Art Unit: 1616

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1616

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over ISENRING et al. (United States Patent No. 6407,100) and JAUTELAT et al. (US Patent 5,789,430). These references teach the compounds as antimicrobial agents, which embraces Applicant's claimed invention.

ISENRING teaches trifloxystrobin as fungicide. See the entire document especially lines 10-20 in column 1, lines 34-67 in column 6, abstract, and examples.

JAUTELAT teaches prothioconazole and tebuconazoles as microbicides. See the entire document especially example 1 in column 35, lines 27-64 in column 29, lines 1-55 in column 30 and Table 1 in column 14.

Instant claims differ from the reference in claiming the combination of all three known compounds useful as antimicrobial and antifungal agents.

It would have been obvious to one skilled in the art at the time of invention was made to combine known compounds for the same purpose in expectation to get a better activity. Since all the above cited reference teach the active compounds as claimed it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a new composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 205 USPQ 1069.

The results presented in the specification on page 11 are not synergistic rather it would have been obvious to one skilled in the art to combine the known active compounds in different ratios. The difference in synergistic efficacy 78 and compound of formula 1 (efficacy 67) does not represent synergism. The data presented in Table

Art Unit: 1616

A on page 11 of the specification is Pyrenophora teres test on barley (now declaration includes two more examples). The synergism as claimed cannot be predicted for the effect on any other phytopathogenic fungi.

Further the legally accepted definition of synergism as meaning "the combined action of two or more agents * * * that is greater than the sum of the action of one of the agents used alone" is cited in In re Luvisi et al, 144 USPQ 646 . In re Lemin et al, 161 USPQ 288 points out the necessity of presenting data for each component singly at the total rate applied in combination in addition to the fact that each component must be tested individually at the rate at which it appears in combination.

In present case each component has not been tested individually at the rate at which it appears in combination.

Applicant's specification discloses that all the compounds in claim 6 are known.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Declaration and the data in Specification

The data presented in the declaration filed by Dr. Peter Dahmen has been considered. In example 1 the calculated efficacy 67 and found 75 is not synergistic for *Blumeria graminis*. Example 2 appears to be marginal synergistic for *Fusarium culmorum*. It is clear from the data that the ratio of the three compounds as 1:1:1 does

Art Unit: 1616

not necessarily will act as synergistic on all the fungi. The claimed subject matter is not limited to such a ratio and fungi.

Examiner has considered the data presented in specification on page 11. The application of the compounds (I), (II) and (III) are 100 g/ha and efficacy is 67, 56 and 22 percent respectively. The data presented in Table A on page 11 of the specification is Pyrenophora teres test on barley. The data presented in the specification is not a side by side comparison. The amounts g/ha is 100 for the compounds (I), (II) and (III) when there individual efficacies has been observed. However, when synergism according to present invention was calculated the amounts were 35+30+35. The ratios as disclosed are 10:8.5:10.

At first the synergism as claimed cannot be predicted for the effect on any other phytopathogenic fungi and ratios of the components. Furthermore, because of each compound appears to be well known in the prior art, it would appear that the combination of the compounds would have been obvious in view of MPEP 2144.06 and See Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

The data presented in the specification and in the declaration does not commensurate to the scope of claimed subject matter and does not show any synergism.

Applicant is requested to explain in detail the synergism.

See Ex parte Quadranti where it was held that

"Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of

Art Unit: 1616

combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

"There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

"Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973); In re Klosak , 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); In re Longi , 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); In re Freeman, supra" .

Art Unit: 1616

"Immediately above, we assumed *arguendo* that the results presented were statistically significant. There is in fact no basis for actually making such an assumption, however. No measure of statistical significance in terms either of P values or confidence limits has been presented. This is particularly important where the differences in question are fairly small, as they are here. The irregular nature of the increase in effectiveness as doubled amounts of Compound IIIb are added also gives rise to questions concerning the reproduceability of the tests used and, thus, the significance of the results. Although patent application specifications are generally not held to the same high standard as scholarly scientific publications, in which statistical significance measures are presented routinely almost as a *sine qua non*, where as here, the data in question are relied on as evidence of unobviousness as it effects the ultimate issue under 35 U.S.C. 103, statistical analysis would unquestionably enhance the probative value of that evidence".

See 201 USPQ 193; *In re Kollman and Irwin*; U.S. Court of Customs and Patent Appeals No.78-624; Decided March 15; 595 F2d 48

It was held that "Appellants point to various examples of data presented in the specification as establishing synergism at other than the 1:1 ratio. This position is not well taken. This data satisfies but part of the criteria set to determine if synergism exists. For instance appellants point to the test in table I employing 4 lbs. of the ether in combination with 2 lbs. of fenac. However there is no testing of the ether at 6 lbs. nor the fenac at 6 lbs., i.e. no testing of the individual components at the total amount of the combination employed.

Art Unit: 1616

The legally accepted definition of synergism as meaning "the combined action of two or more agents * * * that is greater than the sum of the action of one of the agents used alone" is cited in *In re Luvisi et al*, 144 USPQ 646 . *In re Lemin et al*, 161 USPQ 288 points out the necessity of presenting data for each component singly at the total rate applied in combination in addition to the fact that each component must be tested individually at the rate at which it appears in combination".

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER